Full Text CA-93-15

RESEARCH IN PUBLIC AND PROFESSIONAL EDUCATION FOR THE PREVENTION AND CONTROL OF SKIN CANCER

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PURPOSE

The National Cancer Institute (NCI) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) invite applications for grants to conduct research on educational strategies for the prevention of melanoma and non-melanoma skin cancers through controlled studies in defined populations. These behavioral studies should be aimed toward reduction of high levels of exposure to natural or artificial ultraviolet light.

HEALTHY PEOPLE 2000

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a PHS-led national activity for setting priority areas. This Request for Applications (RFA), Research in Public and Professional Education for the Prevention and Control of Skin Cancer, is related to the priority area of skin cancer risk

reduction. Potential applicants may obtain a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0 or Summary Report: Stock No. 017-001-00473-1) through the Superintendent of Documents, Government Printing Office, Washington, DC 20402-9325 (telephone 202-783-3238).

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign non-profit and for-profit organizations and by public and private entities such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Foreign institutions are not eligible for First Independent Research Support and Transition (FIRST) (R29) awards. Applications from minority and women investigators are encouraged. Investigators should be capable of assembling a multidisciplinary team including health education specialists responsible for public education interventions, trained medical personnel knowledgeable in skin cancer for professional education interventions, and associated statisticians, research designers, communication specialists, etc., for the successful implementation and reporting of a full-scale research project.

MECHANISM OF SUPPORT

This RFA will use the National Institutes of Health (NIH) research project grant (R01), and the First Independent Research Support and Transition (FIRST) award (R29). It is anticipated that the average direct costs for each award will be $183,000 per year. This is a one-time solicitation. Future unsolicited competing continuation applications will compete with investigator-initiated applications and will be reviewed according to customary NIH peer review procedures. Responsibility for the planning, direction, and execution of the proposed project will be that of the applicant.

FUNDS AVAILABLE

It is anticipated that three NCI sponsored awards and one or two NIAMS sponsored awards will be made under this RFA, and that the total expenditures for these grants will not exceed $1,500,000 (total costs) for the first year. This level of support is dependent on the receipt of a sufficient number of applications of high scientific merit. Although this RFA is provided for in the financial plans of the NCI and the NIAMS, awards are contingent on the availability of funds. The project period for studies funded through this RFA may not exceed four years. The anticipated award date is April 1, 1994.

RESEARCH OBJECTIVES

Skin cancer is the fastest rising and most common form of cancer in the United States, accounting for well over 600,000 new cases reported every year, or about one-third of all cancer incidence. Of these cases, about 75 percent are basal cell and 20 percent are squamous cell carcinomas, both of which are highly treatable and rarely metastasize. The remaining 5 percent of skin cancer cases are malignant melanomas, which are far more lethal and currently account for an estimated 32,000 new cases, and more than 6,700 deaths per year. Between 1973 and 1989, the incidence rate for melanoma increased by 80.6 percent, more than any other cancer site, and far greater than the 16.1 percent increase for all sites combined. The mortality rate during the same period for all races and both sexes was 32.1 percent for melanoma, compared to the 6.1 percent cancer mortality rate for all sites combined. Theoretically, however, most skin cancer morbidity, and almost all skin cancer mortality should be preventable.

Solar radiation appears to be the primary risk factor for more than 90 percent of nonmelanoma skin cancer cases, and it has also been linked to melanoma. Evidence for the effect of ultraviolet (UV) light exposure, especially the shorter wavelength UV-B rays, on skin cancer shows that a 1 percent relative increase in UV-B radiation may result in a 2 percent increase in skin cancer incidence. UV-B is the radiation that produces tanning and burning in human skin. Concern about the harmful effects of longer wavelength UV-A rays, which are more common in sunlight though less mutagenic than UV-B rays, is growing among researchers. Overall, data appear to indicate that nonmelanoma skin cancer is related to annual cumulative exposure, and that melanoma may be related to high intensity, intermittent UV radiation exposure (i.e., sunburns) particularly at a young age.

Incidence of skin cancer is also influenced by degree of skin pigmentation and sex. Rates are highest for Whites, lower for Asians, and lowest for Blacks. Skin cancer incidence is also highly influenced by intensity of sunlight as a function of proximity to the equator or high altitude.

It is hypothesized that there may be a growing risk of increased exposure to UV radiation due to depletion of the Earth's atmospheric ozone. The effects of a significant loss of the ozone layer on human health are not precisely known, but scientists speculate that skin cancer rates could increase as a result.

In addition to health risks, the yearly estimated costs of treatment for skin cancer are substantial: approximately $37.6 million for basal cell, $28.2 million for squamous cell, and $99.7 million for malignant melanoma, totalling $165.5 million per year.

Despite the hazards of sunlight exposure, National Health and Nutrition Examination Survey self-report data show that a large proportion of the U.S. population engages in moderate to high sunlight exposure: 61.6 percent of white males, 51.2 percent of white females, 49.8 percent of black males, and 41.6 percent of black females. Accordingly, the need for committed national efforts to reduce exposure to sunlight for the purpose of preventing skin cancer is great, and significant progress is clearly necessary. This is reflected in the U.S. Department of Health and Human Services' goal for the year 2000: "Increase to at least 60 percent the proportion of people of all ages who limit sun exposure, use sunscreens and protective clothing when exposed to sunlight, and avoid artificial sources of ultraviolet light (e.g., sun lamps, tanning booths)".

Thus, based on current knowledge of the risks for skin cancer, the most prudent step, especially for those with light complexions, males, and children, is to limit or protect against UV radiation exposure. Parents and caregivers should see that children receive limited sun exposure. For adults, decreased exposure to sunlight and artificial sources of UV light, and use of protective clothing or sunscreen products shown to be capable of reducing UV rays is advisable. Special care should also be taken by people in lower latitudes and higher altitudes, and by everyone during the summertime, and during the midday.

In addition to primary prevention, screening examinations could reduce the discomfort and cosmetic problems associated with nonmelanoma skin cancer. And most skin cancer deaths could be prevented through early detection of malignant melanoma, where five-year survival rates for localized melanomas may be greater than 90 percent. The appeal of skin cancer screening is great, not only because of this high survival rate, but also because it is noninvasive, quick, regarded as diagnostically reliable, and when part of regular medical practice, has little or no cost. Skin cancer is also probably the foremost cancer that most people can be taught to self-screen for with a moderate degree of reliability. Over 90 percent of melanomas can be recognized by unaided visual examination.

This RFA has two major research objectives related to skin cancer prevention: (1) to study the effects of public education interventions aimed at increasing use of sunscreens and protective clothing, limiting exposure to solar radiation, avoiding artificial methods of tanning, teaching skin self-examination, and improving other behaviors related to skin cancer risk reduction; and (2) to study the effects of professional education interventions aimed at increasing caregivers' awareness of skin cancer, their ability to provide advice, and their knowledge on the importance of screening and early detection for the prevention and control of skin cancers.

Most research will take place through a facility capable of community-based cancer prevention research, and will consist of intervening and measuring change in a sample drawn from a population shown to be at-risk by the investigator. This includes pilot testing survey instruments and techniques for feasibility and acceptability, validating instruments, and assessing participation and adherence rates. Investigators may develop their own, or select from or adapt existing materials or strategies that have been shown to be effective in reducing exposure to ultraviolet radiation, and informing health professionals about the risks associated with skin cancer and the use of screening and early detection. Techniques for validating effectiveness of methods and materials will be the responsibility of investigators. To ensure results that are representative, investigators should randomize subjects into intervention and control groups. These groups should be matched on risk factors such as skin pigmentation, age, sex, ethnicity, type of UV radiation exposure (solar, artificial, high altitude, etc.), and current or past exposure habits. Experimental groups must also be of sufficient size to provide the statistical power to detect significant differences between groups on variables of interest.

Evaluations should be designed to test questions such as: (1) what are the most effective educational conditions that lead to a quantifiable reduction in skin cancer risk behaviors in specific populations?; and (2) what are the most effective educational conditions for increasing professional knowledge on primary prevention, screening, and early detection of skin cancer?

The use of intermediary organizations and the formation of public/private partnerships is strongly encouraged. Investigators should strive to bring together diverse groups such as producers of sunscreen products, voluntary organizations, and organizations such as swimming pools, or golf, yacht, or tennis clubs.

STUDY POPULATIONS

SPECIAL INSTRUCTIONS TO APPLICANTS REGARDING IMPLEMENTATION OF NIH POLICIES CONCERNING INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH STUDY POPULATIONS

NIH policy is that applicants for NIH clinical research grants will be required to include minorities and women in study populations so that research findings can be of benefit to all people at risk of the disease, disorder, or condition under study. Special emphasis should be placed on the need for inclusion of minorities in studies of diseases that disproportionately affect them. This policy is intended to apply to males and females of all ages. If women or minorities are excluded or

inadequately represented in clinical research, particularly in proposed population-based studies, a clear and compelling rationale should be provided.

The composition of the proposed study population must be described in terms of gender and racial or ethnic group. In addition, gender and racial or ethnic issues should be addressed in developing a research design and sample size appropriate for the scientific objectives of the study. This information must be included on grant application form PHS 398 (rev. 9/91) in Sections 1-4 of the Research Plan AND summarized in Section 5, Human Subjects. Applicants are urged to carefully assess the feasibility of including the broadest possible representation of minority groups. However, NIH recognizes that it may not be feasible or appropriate in all research projects to include representation of the full array of United States racial or ethnic minority populations (i.e., Native Americans [including American Indians or Alaskan Natives], Asian/Pacific Islanders, Blacks, Hispanics).

The rationale for studies on single minority population groups should be provided.

For the purpose of this policy, clinical research includes human biomedical and behavioral studies or etiology, epidemiology, prevention (and preventive strategies), diagnosis, or treatment of diseases, disorders or conditions, including, but not limited to, clinical trials.

The usual NIH policies concerning research on human subjects also apply. Basic research or clinical studies in which human tissues cannot be identified or linked to individuals are excluded. However, every effort should be made to include human tissues from women and racial/ethnic minorities to enable results of the study to be applied broadly.

For foreign awards, the policy on inclusion of women applies fully; since the definition of minority differs in other countries, applicants must discuss the relevance of research involving foreign population groups to the United States' populations, including minorities.

If the required information is not contained within the application, the application will be returned.

Peer reviewers will specifically address whether the research plan in the application conforms to these policies. If the representation of women or minorities in a study design is inadequate to answer the scientific question(s) addressed AND the justification for the selected study population is inadequate, it will be considered a scientific weakness or deficiency in the study design and will be reflected in assigning a priority score to the application.

All applications for clinical research submitted to NIH are required to address these policies. NIH funding components will not award grants that do not comply with these policies.

LETTER OF INTENT

Prospective applicants are requested to submit, by March 15, 1993, a letter of intent that includes a descriptive title of the proposed research, the name, address, and telephone number of the Principal Investigator, the identities of other key personnel and participating institutions, and the number and title of this RFA.

Although a letter of intent is not required, is not binding, and does not enter into the review of the subsequent application, the information that it contains is helpful in planning for the review of applications. It allows NIH staff to estimate the potential review workload, and helps to avoid conflict of interest among reviewers.

The letter of intent is to be sent to:

D. Michael Anderson, Ph.D., M.P.H.
Director, Skin Cancer Prevention Research
National Cancer Institute
Executive Plaza North, Room 218
Bethesda, MD 20892
Telephone: (301) 496-8577
FAX: (301) 496-8675

or

Alan N. Moshell, M.D.
Skin Disease Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 402-3342
FAX: (301) 480-7881

APPLICATION PROCEDURES

The research grant application form PHS 398 (rev. 9/91) is to be used in applying for this RFA. These forms are available at most institutional offices of sponsored research and may be obtained from the Office of Grant Inquires, Division of Research Grants, National Institutes of Health, Westwood Building, Room 449, Bethesda, MD 20892, telephone 301/496-7441.

The RFA label available in the PHS 398 application kit must be affixed to the bottom of the face page of the application. Omission of this label could result in delayed processing of the application and its failure to reach the review committee in time for review. In addition, the number and title of this RFA must be typed on line 2a on the face page of the application, and the YES box must be marked.

A signed, typewritten original of the application, including the Checklist, and three signed copies must be sent or delivered in one package to:

Division of Research Grants
National Institutes of Health
Westwood Building, Room 240
Bethesda, MD 20892**

At the time of submission, two additional copies of the application must also be sent to:

Ms. Toby Friedberg
Division of Extramural Activities
National Cancer Institute
Executive Plaza North, Room 650
Bethesda, MD 20892

Applications must be received by May 20, 1993. An application received after that will be returned to the applicant. The Division of Research Grants (DRG) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. The DRG will not accept any application that is essentially the same as one already reviewed. This does not preclude the submission of substantial revisions of applications already reviewed, but such applications must include an introduction addressing the previous critique.

REVIEW CONSIDERATIONS

Upon receipt, applications will be reviewed by NCI staff for completeness and responsiveness. Incomplete applications will be returned to the sender without further consideration. If the application is not responsive to the RFA, NCI staff will contact the applicant to determine whether to return the application to the applicant or submit it for review in competition with unsolicited applications in the next review cycle.

Applications may undergo triage by an NCI peer review group on the basis of relative competitiveness. The NCI will withdraw from further competition those applications judged to be non- competitive for award and notify the application's Principal Investigator and institutional official. Those applications that are judged to be complete and responsive will be evaluated in accordance with the criteria stated below for scientific or technical merit by an appropriate peer review group convened by the NCI. The second level of review will be provided by the National Cancer Advisory Board or the National Arthritis and Musculoskeletal and Skin Disease Advisory Council.

Review criteria include, but are not limited to:

o scientific significance and originality of proposed research;

o appropriateness and adequacy of the experimental design and methodology proposed to carry out the research;

o qualifications and research experience of the Principal Investigator and staff, particularly in the area of the proposed research;

o availability of resources necessary to carry out the research;

o availability of, and capacity to recruit, adequate numbers of subjects for statistically significant research outcomes.

The review group will also critically examine the submitted budget and will recommend an appropriate budget and period of support for each approved application.

AWARD CRITERIA

The anticipated date of award is April 1, 1994.

Applications considered responsive will be reviewed by an Initial Review Group (IRG). IRGs are allowed two types of recommendations; they may give an application a priority score, or they may suggest that an application be "not recommended for further consideration" (NRFC). Availability of funds, geographic distribution of awards, characteristics of study populations, and other programmatic priorities are also important criteria in making grant awards.

INQUIRIES

Written and telephone inquiries concerning the objectives and scope of this RFA, whether or not specific proposed research is responsive, the scientific content and objectives of an application, the size and focus of a research program, and the organization of an application, are strongly encouraged and may be directed to:

D. Michael Anderson, Ph.D., M.P.H.
Director, Skin Cancer Prevention Research
National Cancer Institute
Executive Plaza North, Room 218
Bethesda, MD 20892
Telephone: (301) 496-8577

or

Alan N. Moshell, M.D.
Skin Disease Program Director
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 405
Bethesda, MD 20892
Telephone: (301) 402-3342

Requests for information on fiscal policies may be directed to:

Eileen Natoli
Grants Administration Branch
National Cancer Institute
Executive Plaza South, Room 242
Bethesda, MD 20892
Telephone: (301) 496-7800, ext. 56

or

Diane Watson
Extramural Research Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
Westwood Building, Room 720
Bethesda, MD 20892
Telephone: (301) 402-3352

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance No. 93.399. Grants will be awarded under the authority of the Public Health Service Act, Title IV, Part A (Public Law 78-410, as amended by Public Law 99-158, 42 USC 241 and 285) and administered under PHS grants policies and Federal Regulations 42 CFR Part 52 and 45 CFR Part 74. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

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